K031218

MAY 1 6 2003

# TORNIER

**Implants Chirurgicaux**

## Summary of Safety and Effectiveness information
## Special 510(k) – Tornier Total Elbow Prosthesis

**Regulatory authority:** Safe Medical Devices Act of 1990, 21 CRF 807.92

**1) Device name**

**Trade name:** ***Tornier Total Elbow Prosthesis***
**Common name:** Total Elbow Prosthesis
**Classification name:** Elbow joint metal/polymer semi-constrained cemented prosthesis
Elbow joint metal/metal or metal/polymer constrained cemented prosthesis

**2) Submitter**

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

**3) Company contact**

Tornier S.A.
Mrs Mireille Lémery
Regulatory affairs & Quality Engineer
ZIRST - 161, rue Lavoisier
38330 Montbonnot - France
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Fax: 00 33 4 76 61 35 33
e-mail : mireille.lemery@tornier.fr

**4) Classification**

**Device class:** Class II
**Classification panel:** Orthopedic
**Product code:** JDB and JDC
§ **888.3160** Elbow joint metal/polymer semi-constrained cemented prosthesis
§ **888.3150** Elbow joint metal/metal or metal/polymer constrained cemented prosthesis

**5) Equivalent / Predicate device**

Coonrad / Morrey Total Elbow, Zimmer (K973357)
Sorbie - Questor Elbow System, Wright (K955099)
Tornier Total Elbow Prosthesis, Tornier (K000003 and K011567)



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S.A. au capital de 1 800 000 F
SIRET : 070 501 275 000 13
R.C.S. : B 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : B.P. 11 - rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

**6) Device description**

Total Elbow replacement are used to treat a number of clinical conditions such are severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint. It is also used in revision procedures where other treatments or devices have failed and treatment of fractures that are unmanageable using other techniques. The usual goal of such surgery is to restore the elbow joint to its best working condition and to reduce or eliminate pain. The Tornier Total Elbow Prosthesis is intended to accomplish these goals. The Tornier Elbow prosthesis is intended for use as a cemented total elbow.

The present Device Modification submission corresponds to :

- the addition of one ulnar longer stem with the same diameter to the previous range with the same indications for use already covered by the previous 510(k) clearance,
- the addition of the possibility to manufacture some components in an other grade of CoCr alloy, the manufacturing method is unchanged compared to the previous 510(k) clearance,
- the modification of the locking mechanism of the ulnar cap.

**7) Materials**

Humeral implant components are available in CoCr alloy according to standard ISO 5832-7 or ISO 5832-12 or ISO 5832-4. The ulnar and radial components are made of CoCr alloy according to standard ISO 5832-7 or ISO 5832-12 or ISO 5832-4, and UHMWPE according to standard ISO 5834-2.

**8) Indications**

The *Tornier Total Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated in the following cases: to relieve severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint; correction of functional deformities; revision procedures where other treatments or device have failed; treatment of fractures that are unmanageable using other techniques.

The *Tornier Total Elbow Prosthesis* is intended for cemented use only.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2003

Ms. Mireille Lémery
Regulatory Affairs & Quality Engineer
Tornier S.A.
ZIRST – 161, rue Lavoisier
38330 Montbonnot - France

Re: K031218
Trade/Device Name: Tornier Total Elbow Prosthesis
Regulation Numbers: 21 CFR 888.3150; 21 CFR 888.3160
Regulation Names: Elbow joint metal/polymer constrained cemented prosthesis, Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JDC, JDB
Dated: April 2, 2003
Received: April 17, 2003

Dear Ms. Lémery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number** (if known): K031218

**Device name:** ***Tornier Total Elbow Prosthesis***

**Indication for use:**

The *Tornier Total Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated in the following cases: to relieve severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint; correction of functional deformities; revision procedures where other treatments or device have failed; treatment of fractures that are unmanageable using other techniques.

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031218

Prescription use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)